REMARKS

35 USC §112

The Examiner has rejected claims 1-32 as failing to comply with the written description requirements of 35 USC §112, first paragraph. Applicants have amended claim 1 as suggested by the Examiner to be limited to nicotine actives and, thus, respectfully ask for withdrawal of this rejection.

The Examiner has rejected claims 9-11 and 18 as being indefinite under 35 USC §112 for insufficient antecedent basis for the phrases "said gum" and "the nicotine active", respectively. Applicants have amended claims 1 and 9-11 to clarify what is being claimed. Therefore, Applicants respectfully request withdrawal of this rejection.

Specification

The Examiner has objected to the specification as failing to provide proper antecedent basis for the phrase "prior to ingestion" as recited in claim 6. Applicants have submitted herewith an amendment to the specification to incorporate this language, as suggested by the Examiner. This amendment does not constitute new matter.

35 USC §102

The Examiner has rejected claims 1-11, 13-16, 22, 26, 27 and 32 as being anticipated by US 5,167,964 to Muhammad et al (hereinafter "Muhammad").

Muhammad relates to a semi-enteric drug delivery system which comprises an inert core, a first coating layer over the core which comprises a medicament and a second coating layer over the first coating layer comprising an aqueous dispersion of an anionic copolymer based on methacrylic acid and ethylacrylate and povidone. These semi-enteric drug delivery systems may then be formulated with conventional additives or may be incorporated within a hard or soft confectionery composition. *See Muhammad*, column 8, lines 11-20. It is this hard confectionery form that the Examiner asserts is the same as the compositions of the present invention.

Applicants maintain that the present invention is not anticipated by the teachings of Muhammad.

The present invention, relates to a dosage form comprising a glassy matrix (or base) comprising at least one substantially non-hygroscopic sugar alcohol capable of forming a glassy structure, a water soluble gelling gum present in an amount which provides an oral dissolution rate of said glassy matrix ***such that a desired amount of a nicotine active is delivered via the oral mucosa prior to ingestion into the stomach***, and wherein the nicotine active is substantially contained within the glass matrix.

The present invention differs from that of Muhammad in at least two important aspects. First, there is no teaching in Muhammad that the hard confectionery dosage forms which comprise the semi-enteric drug delivery systems taught therein may contain a water soluble gelling gum. The only mention of such gums within the disclosure of Muhammad appears at column 11, lines 1-6 wherein it is taught that thickeners may be added to pharmaceutical suspensions comprising the semi-enteric drug delivery systems taught therein – not the hard confection dosage forms which were previously described. There is no motivation in Muhammad to alter those hard confection dosage forms to further comprise a "thickener" like the suspensions described therein.

Second, Muhammad cannot be said to teach or suggest that the hard confections described by Muhammad should be modified to include water soluble gelling gums, ***particularly at the levels taught by the present invention***, i.e. an amount which provides an oral dissolution rate of said glassy matrix such that a desired amount of a nicotine active is delivered via the oral mucosa prior to ingestion into the stomach. The term "semi-enteric" as defined by Muhammad relates to a delivery system that partially releases medicament in the stomach and thereafter releases additional medicament in the intestines for delayed release. *See Muhammad,* column 2, lines 28-32. There is no suggestion that oral dissolution rates providing oral absorption of an active would be desirable for the compositions of Muhammad. Thus, there is no teaching or suggestion in Muhammad the hard

confection formulations disclosed therein could include a water soluble gelling gum at a level sufficient to provide an oral dissolution rate such that a desired amount of active agent, such as nicotine, would be delivered via the oral mucosa.

Therefore, Applicants respectfully request that the Examiner's rejections based on Muhammad pursuant to 35 USC §102 be withdrawn.

35 USC §103

The Examiner rejects claim 32 under 35 USC §103 (a) as being rendered obvious by Muhammad.

The Examiner further rejects claims 12, 21 and 25 under 35 USC §103(a) as being obvious in light of Muhammad in view of Rapp et al. (US 6,180,143 B1, hereinafter "Rapp") or Burnick et al. (US2003/0017202 A1, hereinafter "Burnick"). Applicant maintains that Muhammad, taken alone or in combination with either Rapp or Burnick does not render claims 12, 21 or 25 obvious.

For the reasons stated above, Applicants believe that Muhammad does not teach each and every element of the claimed invention. That is, Muhammad does not disclose a dosage form comprising a glassy matrix (or base) comprising at least one substantially non-hygroscopic sugar alcohol capable of forming a glassy structure, a water soluble gelling gum present in an amount which provides an oral dissolution rate of said glassy matrix ***such that a desired amount of a nicotine active is delivered via the oral mucosa prior to ingestion into the stomach***, and wherein the nicotine active is substantially contained within the glass matrix. Further, Muhammad cannot be said to suggest each and every element of the claimed invention as the focus in Muhammad is to provide semi-enteric formulations with partial active delivery in the stomach and partial active delivery in the intestines. There is no motivation to modify the teaching of Muhammad to ensure that a desired amount of a nicotine active is delivered via the oral mucosa prior to ingestion into the stomach.

The Examiner relies on Rapp and Burnick for the principle that sweetening agents, such as ISOMALT, are known for use in nicotine formulations. Rapp relates to chewing gum compositions which may comprise 1,1-GPS alone or in combination with other sweeteners. Such sweeteners are incorporated into the

Rapp compositions to increase flexibility of the gum and prevent drying out of the gum during storage. Burnick relates to an oral dosage form comprising a soft core encased within a brittle shell coating that also my include sweeteners of the type described above.

Clearly, neither Rapp nor Burnick relates to an oral dosage form comprising a glassy matrix of a non-hygroscopic sugar alcohol which substantially contains an active agent therein, as a glassy matrix would not provide an acceptable chewing gum or chewable soft core composition. Thus the combination of either of these references with Muhammad would not result in the compositions of the present invention, in particular, a dosage form comprising a glassy matrix, within which a nicotine active is substantially contained, comprising at least one substantially non-hygroscopic sugar alcohol capable of forming a glassy structure and a water soluble gelling gum present in an amount which provides an oral dissolution rate of said glassy matrix such that a desired amount of the nicotine active is delivered via the oral mucosa prior to ingestion into the stomach.

Therefore, Applicant respectfully requests that the Examiner's rejections based on 35 USC §103(a) in light of Muhammad in combination with Rapp or Burnick, be withdrawn.

In light of the amendments submitted herewith and the accompanying remarks, Applicants believe that all objections and rejections raised by the Examiner have been addressed. Thus, Applicants respectfully request withdrawal of the rejections under 35 USC §112, §102 and §103 and allowance of all claims that remain pending.

Respectfully submitted,

Andrea L. Winslow
Attorney for Applicants
Registration No. 48,586

GLAXOSMITHKLINE
Corporate Intellectual Property-UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Tel: 610 270 7513; Fax: 610 270 5090
Email: Andrea.L.Winslow@gsk.com
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